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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665
7590	04/11/2005		EXAMINER TRAN, SUSAN T	
Richard M Klein Fay Sharpe Fagan Minnich & McKee 1100 Superior Avenue Seventh Floor Cleveland, OH 44114			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,340

Applicant(s)

SHODAI ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/04/04.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 03/31/05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 11/04/04, Amendment, and Request for Extension of Time filed 10/22/04.

Claim Objections

Claims 7, 8 and 31-33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 7 and 8 recite "according to any one of claims 1 to 6", nonetheless, there is not supposed to be 1 to 6, because claim 3 has been cancelled. Applicant is required to amend the claims to place them in proper dependent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite in the use of the phrase "further comprises, lard, coconut oil and macrogol as well as a combination thereof". The first part of the phrase "comprises, lard, coconut oil *and* macrogol" appears to be a combination of all three components, therefore, the phrase "as well as a combination thereof" is redundant and confusing.

Claim 8 is rejected in the use of the phrase "low melting point further comprises". It appears that the word "additive" was inadvertently being deleted.

Claim 31 is indefinite in the use of the phrase "further comprises". The claim fails to further limit the subject matter of claim 8. Claim 8 has already recite the "further comprises" of the components, claim 31 further limit claim 8, therefore, it is suggested to replace the phrase "further comprises" with the word "is".

Claim 32 is indefinite in the use of the phrase "further comprises". The claim fails to further limit the subject matter of claim 8. Claim 8 has already recite the "further comprises" of the components, claim 31 further limit claim 8, therefore, it is suggested to replace the phrase "further comprises" with the word "is".

Claim 33 is indefinite in the use of the phrase "further comprises". The claim fails to further limit the subject matter of claim 8. Claim 8 has already recite the "further comprises" of the components, claim 31 further limit claim 8, therefore, it is suggested to replace the phrase "further comprises" with the word "is".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4-6, 10, 24, 26, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheibl US 4,724,136.

Scheibl discloses a confectionery preparation in the form of chewable capsules, tablets, chewing gums, wafer and the like comprising a fill material (see abstract; and column 1, lines 30-55). The fill material comprises cacao powder, flavoring and coloring agents (example 1). The filled further comprises drugs or active agents disclosed in column 2, lines 51-65.

Claims 1, 2, 4-6, 10, 12, 13, 15-17 and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Dugger, III US 5,955,098.

Dugger discloses a soft bite gelatin capsule comprising a paste fill composition contains flavoring agent, sweetening agent, active compound, and excipient (see abstract, column 3, lines 12-62). Example 12 discloses a capsule fill comprising chocolate powder in an amount of about 46.67%, and nicotine (active agent) in an amount of 0.185%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-7, 10-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Borkan et al. US 4,935,243.

Scheibl or Dugger, III is relied upon for the reason stated above. The references do not explicitly teach the capsule shell as claimed in claim 19. However Dugger incorporates Borkan by reference for the teaching of chewable soft gelatin capsule.

Borkan teaches a chewable, edible soft gelatin capsule comprising a solid or semi-solid fill material (see abstract; and column 3, lines 1-5). The gelatin shell comprises gelatin, glycerin as a plasticizer, D-sorbitol, and sweetener (columns 3-4; and column 5, lines 1-36). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable, edible soft gelatin capsule of Borkan to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claims 1, 2, 4-7, 10-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Ebert et al. US 4532126.

Scheibl or Dugger, III is relied upon for the reason stated above. Neither Scheibl nor Dugger explicitly teach the capsule shell as claimed in claim 19.

Ebert teaches a chewable soft gelatin capsule comprising gelatin, water, a plasticizer and a masticatory substance (Col. 54-68). The plasticizer is glycerin or sorbitol (Col. 2, lines 54-60). The capsule is filled with candy confectionaries, antacids, cough preparations, cold preparations, sore throat remedies, antiseptics, dental preparations, dextromethorphan, and/or acetaminophen (Col. 3, line 67 - Col. 4, line 3; Col. 5; Example 11; Col. 6, Example IV). The capsules also contain taste modifiers or

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flavoring agents (Col. 4, lines 13-25). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable soft gelatin capsule of Ebert to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Mehta US 5,084,278.

Neither Scheibl nor Dugger does teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to use chocolate flavor as the flavoring agent for the fill material taught by Scheibl or Dugger, because the references teach the use of flavoring agent suitable for taste masking of active agents acceptable for chewing composition.

Pertinent Arts

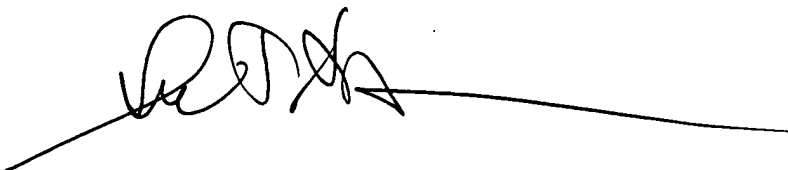
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Maddox and Liu et al. are cited as of interest for the teachings of gelatin capsule containing chocolate.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', is written over a horizontal line.

Susan T. Tran
Examiner
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